General

Guideline Title

(1) Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline. (2) Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline focused update.

Bibliographic Source(s)

Harris LN, Ismaila N, McShane LM, Andre F, Collyar DE, Gonzalez-Angulo AM, Hammond EH, Kuderer NM, Liu MC, Mennel RG, Van Poznak C, Bast RC, Hayes DF. Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline. J Clin Oncol. 2016 Apr 1;34(10):1134-50. [82 references] PubMed

Krop I, Ismaila N, Andre F, Bast RC, Barlow W, Collyar DE, Hammond ME, Kuderer NM, Liu MC, Mennel RG, Van Poznak C, Wolff AC, Stearns V. Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline focused update. J Clin Oncol. 2017 Aug 20;35(24):2838-47. [17 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source

▮▮▮▮▮	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition
YES	Multidisciplinary Group
YES	Methodologist Involvement
▮▮▮▮▮	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▮	Search Strategy
▮▮▮▮▮	Study Selection
▮▮▮▮▮	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▮	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▮▮	Rating the Strength of Recommendations
▮▮▮▮▮	Specific and Unambiguous Articulation of Recommendations
▮▮▮▯▯	External Review
▮▮▮▮▮	Updating

Recommendations

Major Recommendations

Definitions for the rating of evidence (High, Intermediate, Low, Insufficient); types of recommendations (Evidence based, Formal consensus, Informal consensus, No recommendation); and strength of recommendations (Strong, Moderate, Weak) are provided at the end of the "Major Recommendations" field.

Clinical Question 1

For women with early-stage invasive breast cancer and with known estrogen and progesterone receptor (ER/PgR) and human epidermal growth factor receptor 2 (HER2) status, which other biomarkers have demonstrated clinical utility to guide decisions on the need for adjuvant systemic therapy?

Recommendation 1.1: If a patient has ER/PgR-positive, HER2-negative (node-negative) breast cancer, the

clinician may use the 21-gene recurrence score (RS) (Oncotype DX; Genomic Health, Redwood City, CA) to guide decisions on adjuvant systemic chemotherapy (Type: evidence based; Evidence quality: high; Strength of recommendation: strong).

Recommendation 1.2: If a patient has ER/PgR-positive, HER2-negative (node-positive) breast cancer, the clinician should not use the 21-gene RS (Oncotype DX) to guide decisions on adjuvant systemic chemotherapy (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: moderate).

Recommendation 1.3: If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use the 21-gene RS (Oncotype DX) to guide decisions on adjuvant systemic therapy (Type: informal consensus; Evidence quality: insufficient; Strength of recommendation: strong).

Recommendation 1.4: If a patient has ER/PgR-positive, HER2-negative (node-negative) breast cancer, the clinician may use the 12-gene risk score (EndoPredict; Sividon Diagnostics, Köln, Germany) to guide decisions on adjuvant systemic chemotherapy (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: moderate).

Recommendation 1.5: If a patient has ER/PgR-positive, HER2-negative (node-positive) breast cancer, the clinician should not use the 12-gene risk score (EndoPredict; Sividon Diagnostics) to guide decisions on adjuvant systemic chemotherapy (Type: evidence based; Evidence quality: insufficient; Strength of recommendation: moderate).

Recommendation 1.6: If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use the 12-gene risk score (EndoPredict; Sividon Diagnostics) to guide decisions on adjuvant systemic therapy (Type: informal consensus; Evidence quality: insufficient; Strength of recommendation: strong).

Recommendation 1.7 (1.1.1 in 2017): If a patient has ER/PgR-positive, HER2-negative, node-negative breast cancer, the MammaPrint (Agendia, Irvine, CA) assay may be used in those with high clinical risk per MINDACT (Microarray in Node-Negative and 1 to 3 Positive Lymph Node Diseases May Avoid Chemotherapy) categorization to inform decisions on withholding adjuvant systemic chemotherapy due to its ability to identify a good-prognosis population with potentially limited chemotherapy benefit (Type: evidence based; Evidence quality: high; Strength of recommendation: strong).

Recommendation 1.7 (1.1.2 in 2017): If a patient has ER/PgR–positive, HER2-negative, node-negative breast cancer, the MammaPrint (Agendia) assay should not be used in those with low clinical risk per MINDACT categorization to inform decisions on withholding adjuvant systemic chemotherapy, because women in the low clinical risk category had excellent outcomes and did not appear to benefit from chemotherapy even with a genomic high-risk cancer (Type: evidence based; Evidence quality: high; Strength of recommendation: strong).

Recommendation 1.7 (1.2.1 in 2017): If a patient has ER/PgR–positive, HER2-negative, node-positive breast cancer, the MammaPrint (Agendia) assay may be used in patients with one to three positive nodes and at high clinical risk per MINDACT categorization to inform decisions on withholding adjuvant systemic chemotherapy due to its ability to identify a good prognosis population with potentially limited chemotherapy benefit. However, such patients should be informed that a benefit of chemotherapy cannot be excluded, particularly in patients with greater than one involved lymph node (Type: evidence based; Evidence quality: high; Strength of recommendation: moderate).

Recommendation 1.7 (1.2.2 in 2017): If a patient has ER/PgR–positive, HER2-negative, node-positive breast cancer, the MammaPrint (Agendia) assay should not be used in patients with one to three positive nodes and at low clinical risk per MINDACT categorization to inform decisions on withholding adjuvant systemic chemotherapy. There are insufficient data on the clinical utility of MammaPrint in this specific patient population (Type: informal consensus; Evidence quality: low; Strength of recommendation: moderate).

Recommendation 1.8 (1.3 in 2017): If a patient has HER2-positive breast cancer, the clinician should not

use the MammaPrint (Agendia) assay to guide decisions on adjuvant systemic therapy. Additional studies are required to address the role of MammaPrint in patients with this tumor subtype who are also receiving HER-2-targeted therapy (Type: informal consensus; Evidence quality: low; Strength of recommendation: moderate).

Recommendation 1.9 (1.4 in 2017): If a patient has ER/PgR–negative and HER2-negative breast cancer (triple-negative), the clinician should not use the MammaPrint (Agendia) assay to guide decisions on adjuvant systemic chemotherapy (Type: informal consensus; Evidence quality: insufficient; Strength of recommendation: strong).

Recommendation 1.10: If a patient has ER/PgR-positive, HER2-negative (node-negative) breast cancer, the clinician may use the PAM50 risk of recurrence (ROR) score (Prosigna Breast Cancer Prognostic Gene Signature Assay; NanoString Technologies, Seattle, WA) in conjunction with other clinicopathologic variables to guide decisions on adjuvant systemic therapy (Type: evidence based; Evidence quality: high; Strength of recommendation: strong).

Recommendation 1.11: If a patient has ER/PgR-positive, HER2-negative (node-positive) breast cancer, the clinician should not use the PAM50-ROR score (Prosigna Breast Cancer Prognostic Gene Signature Assay; NanoString Technologies) to guide decisions on adjuvant systemic therapy. (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: moderate).

Recommendation 1.12: If a patient has HER2-positive breast cancer, the clinician should not use the PAM50-ROR score (Prosigna Breast Cancer Prognostic Gene Signature Assay; NanoString Technologies) to guide decisions on adjuvant systemic therapy (Type: informal consensus; Evidence quality: insufficient; Strength of recommendation: strong).

Recommendation 1.13: If a patient has triple-negative breast cancer, the clinician should not use the PAM50-ROR score (Prosigna Breast Cancer Prognostic Gene Signature Assay; NanoString Technologies) to guide decisions on adjuvant systemic therapy (Type: informal consensus; Evidence quality: insufficient; Strength of recommendation: strong).

Recommendation 1.14: If a patient has ER/PgR-positive, HER2-negative, node-negative breast cancer, the clinician may use the Breast Cancer Index (bioTheranostics, San Diego, CA) to guide decisions on adjuvant systemic therapy (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: moderate).

Recommendation 1.15: If a patient has ER/PgR-positive, HER2-negative, node-positive breast cancer, the clinician should not use the Breast Cancer Index (bioTheranostics) to guide decisions on adjuvant systemic therapy (Type: informal consensus; Evidence quality: insufficient; Strength of recommendation: strong).

Recommendation 1.16: If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use the Breast Cancer Index (bioTheranostics) to guide decisions on adjuvant systemic therapy (Type: informal consensus; Evidence quality: insufficient; Strength of recommendation: strong).

Recommendation 1.17: If a patient has ER/PgR-positive, HER2-negative (node-positive or node-negative) breast cancer, the clinician should not use the five-protein assay Mammostrat (GE Healthcare, Aliso Viejo, CA) to guide decisions on adjuvant systemic therapy (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: moderate).

Recommendation 1.18: If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use the five-protein assay Mammostrat (GE Healthcare) to guide decisions on adjuvant systemic therapy (Type: informal consensus; Evidence quality: insufficient; Strength of recommendation: strong).

Recommendation 1.19: If a patient has ER/PgR-positive, HER2-negative (node-positive or node-negative) breast cancer, the clinician should not use the immunohistochemistry 4 (IHC-4) assay to guide decisions

on adjuvant systemic chemotherapy (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: moderate).

Recommendation 1.20: If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use IHC-4 to guide decisions on adjuvant systemic therapy (Type: informal consensus; Evidence quality: insufficient; Strength of recommendation: strong).

Recommendation 1.21: If a patient has ER/PgR-positive, HER2-negative (node-negative) breast cancer, the clinician may use the urokinase plasminogen activator (uPA) and plasminogen activator inhibitor type 1 (PAI-1) to guide decisions on adjuvant systemic therapy (Type: evidence based; Evidence quality: high; Strength of recommendation: weak).

Recommendation 1.22: If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use the uPA and PAI-1 to guide decisions on adjuvant systemic therapy (Type: informal consensus; Evidence quality: insufficient; Strength of recommendation: weak).

Recommendation 1.23: The clinician should not use circulating tumor cells (CTCs) to guide decisions on adjuvant systemic therapy (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: strong).

Recommendation 1.24: If a patient has ER/PgR-positive, HER2-negative (node-positive or node-negative) breast cancer, the clinician should not use tumor-infiltrating lymphocytes (TILs) to guide decisions on adjuvant systemic therapy (Type: informal consensus; Evidence quality: insufficient; Strength of recommendation: strong).

Recommendation 1.25: If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use TILs to guide decisions on adjuvant systemic therapy (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: strong).

Recommendation 1.26: Ki-67 labeling index by IHC should not be used to guide the choice of adjuvant chemotherapy (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: moderate).

Recommendation 1.27: If a patient has ER/PgR-positive, HER2-negative (node-negative) breast cancer and has had 5 years of endocrine therapy without evidence of recurrence, the clinician should not use multiparameter gene expression or protein assays (Oncotype DX, EndoPredict, PAM50, Breast Cancer Index, or IHC-4) to guide decisions on extended endocrine therapy (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: moderate).

Clinical Question 2

For women with early-stage invasive breast cancer and with known ER/PgR and HER2 status, which additional biomarkers have demonstrated clinical utility to guide choice of specific drugs or regimens for adjuvant systemic therapy?

Recommendation 2.1: The clinician should not use cytochrome P450 2D6 (*CYP2D6*) polymorphisms to guide adjuvant endocrine therapy selection (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: moderate).

Recommendation 2.2: The clinician should not use p27 expression by IHC to guide adjuvant endocrine therapy selection (Type: informal consensus; Evidence quality: low; Strength of recommendation: strong).

Recommendation 2.3: The clinician should not use Ki-67 labeling index by IHC to guide adjuvant endocrine therapy selection (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: moderate).

Recommendation 2.4: The clinician should not use microtubule-associated protein (MAP)-Tau messenger ribonucleic acid (mRNA) expression or mRNA expression by IHC to guide adjuvant chemotherapy selection (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: moderate).

Recommendation 2.5: The clinician should not use HER1/epidermal growth factor receptor (EGFR) expression by IHC to guide adjuvant chemotherapy selection (Type: evidence based; Evidence quality: low; Strength of recommendation: moderate).

Recommendation 2.6: The clinician should not use topoisomerase IIα (*TOP2A*) gene amplification or TOP2A protein expression by IHC to guide adjuvant chemotherapy selection (Type: evidence based; Evidence quality: high; Strength of recommendation: moderate).

Recommendation 2.7: The clinician should not use *HER2* and *TOP2A* gene coamplification; chromosome 17 centromere (CEP17) duplication; or tissue inhibitor of metalloproteinase 1 (TIMP-1), Forkhead Box Protein 3 (FOXP3), or p53 protein expression to guide adjuvant chemotherapy selection (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: moderate).

Recommendation 2.8: If a patient has HER2-positive breast cancer, the clinician should not use phosphatase and tensin homolog (PTEN) to guide adjuvant therapy selection (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: moderate).

Recommendation 2.9: If a patient has HER2-positive breast cancer, the clinician should not use soluble HER2 levels to guide adjuvant therapy selection (Type: evidence based; Evidence quality: low; Strength of recommendation: moderate).

Definitions

Guide for Rating Quality of Evidence

Rating for Strength of Evidence	Definition
High	High confidence that the available evidence reflects the true magnitude and direction of the net effect (i.e., balance of benefits versus harms) and that further research is very unlikely to change either the magnitude or direction of this net effect.
Intermediate	Moderate confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research is unlikely to alter the direction of the net effect; however, it might alter the magnitude of the net effect.
Low	Low confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research may change either the magnitude and/or direction this net effect.
Insufficient	Evidence is insufficient to discern the true magnitude and direction of the net effect. Further research may better inform the topic. The use of the consensus opinion of experts is reasonable to inform outcomes related to the topic.

Guide for Types of Recommendations

Type of Recommendation	Definition
Evidence based	There was sufficient evidence from published studies to inform a recommendation to guide clinical practice.
Formal consensus	The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. Therefore, the Expert Panel used a formal consensus process to reach this recommendation, which is considered the best current guidance for practice. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak"). The results of the formal consensus process are summarized in the guideline and reported in the Data Supplement (see the "Availability of Companion Documents" field).
Informal Consensus	The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. The recommendation is considered the best current guidance for practice, based on informal consensus of the Expert Panel. The Panel agreed that a formal consensus process was not necessary for reasons described in the literature review and discussion. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak").

Type of Recommendation	Definition
No recommendation	There is insufficient evidence, confidence, or agreement to provide a recommendation to guide clinical practice at this time. The Panel deemed the available evidence as insufficient and concluded it was unlikely that a formal consensus process would achieve the level of agreement needed for a recommendation.

Guide for Rating Strength of Recommendations

Rating for Strength of Recommendation	Definition
Strong	There is high confidence that the recommendation reflects best practice. This is based on (1) strong evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with no or minor exceptions; (3) minor or no concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a strong recommendation.
Moderate	There is moderate confidence that the recommendation reflects best practice. This is based on (1) good evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with minor and/or few exceptions; (3) minor and/or few concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a moderate recommendation.
Weak	There is some confidence that the recommendation offers the best current guidance for practice. This is based on (1) limited evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, but with important exceptions; (3) concerns about study quality; and/or (4) the extent of panelists' agreement. Other considerations (discussed in the guideline's literature review and analyses) may also warrant a weak recommendation.

Clinical Algorithm(s)

An algorithm titled "Algorithm on Biomarkers to Guide Decisions on Adjuvant Systematic Therapy" is provided on the American Society of Clinical Oncology (ASCO) Web site .

Scope

Disease/Condition(s)

Early-stage invasive breast cancer

Guideline Category

Evaluation

Treatment

Clinical Specialty

Obstetrics and Gynecology

Oncology

Pathology

Intended Users

Advanced Practice Nurses

Nurses

Patients

Physician Assistants

Physicians

Guideline Objective(s)

2016 Guideline

To provide evidence-based recommendations to practicing oncologists and other stakeholders on the appropriate use of breast tumor biomarker assay results to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer with known hormone receptor (estrogen and progesterone receptors [ER/PgRs]) and human epidermal growth factor receptor 2 [HER2]) status

2017 Addendum

To address the use of MammaPrint to guide decisions on the use of adjuvant systemic therapy

Target Population

Women with early-stage invasive breast cancer under consideration for adjuvant systemic therapy with known estrogen receptor/progesterone receptor (ER/PgR) and human epidermal growth factor receptor 2 (HER2) status

Interventions and Practices Considered

1. 21-gene recurrence score (RS) (Onco*type* DX)
2. 12-gene risk score (EndoPredict)
3. MammaPrint assay
4. PAM50 risk of recurrence (ROR) score (Prosigna Breast Cancer Prognostic Gene Signature Assay)
5. Breast Cancer Index
6. Urokinase plasminogen activator (uPA) and plasminogen activator inhibitor type 1 (PAI-1)
7. Phosphatase and tensin homolog (PTEN) loss
8. Soluble human epidermal growth factor receptor 2 (HER2) levels

Note: Not all of the listed assays are recommended in all target populations; see the "Major Recommendations" field for context. The following were considered but not recommended for any of the populations: five-protein assay (Mammostrat), immunohistochemistry 4 (IHC-4), circulating tumor cells, tumor-infiltrating lymphocytes, Ki-67 labeling index by IHC, cytochrome P450 2D6 (*CYP2D6*) polymorphisms, p27 expression by IHC, microtubule-associated protein (MAP)-Tau messenger ribonucleic acid (mRNA) expression or mRNA expression by IHC, human epidermal growth factor receptor 1 (HER1)/epidermal growth factor receptor (EGFR) expression by IHC, topoisomerase IIα (*TOP2A*) gene amplification or TOP2A protein expression by IHC, *HER2* and *TOP2A* gene coamplification, chromosome 17 centromere (*CEP17*) duplication, tissue inhibitor of metalloproteinase 1 (TIMP-1), Forkhead Box Protein 3 (FOXP3), or p53 protein expression.

Major Outcomes Considered

Survival rate (disease-free, recurrence-free, overall)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

2016 Guideline

Literature Search Strategy

The Expert Panel developed its recommendations based on evidence identified through online searches of Medline and the Cochrane Library (from January 2006 through August 2015, to overlap with the search end date for the 2007 guideline update on tumor markers in breast cancer [Harris et al., 2007]), and their own clinical experience. See Data Supplement 4 (see the "Availability of Companion Documents" field) for full details on the search string. A combined PubMed search was conducted for this guideline and for a similar guideline on use of biomarkers to guide decisions on systemic therapy in metastatic breast cancer, with articles selected for each guideline's systematic review based on the patient population studied. Articles were selected for inclusion in the systematic review based on the following criteria:

- Population: Women with early stage invasive breast cancer being considered for adjuvant systemic therapy, with separate sub-questions and analyses on patient groups with:
  - Hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative disease HER2-positive disease
  - Triple receptor negative disease (estrogen receptor-negative [ER-negative], progesterone receptor-negative [PR-negative], and HER2-negative)
- Publications in English were included if they reported rigorously conducted systematic reviews (with or without meta-analyses), randomized controlled trials (RCTs), retrospective biomarker analyses of samples from completed prospective RCTs, or prospective observational studies that directly compared outcomes of treatment decisions made on the basis of assay results with outcomes of treatment decisions made regardless of assay results.

Articles were excluded from the systematic review if they were (1) meeting abstracts not subsequently published in peer-reviewed journals; (2) editorials, commentaries, letters, news articles, case reports, narrative reviews; (3) published in a non-English language; (4) retrospective observational studies.

2017 Addendum

Update Process

The American Society of Clinical Oncology (ASCO) uses a signals approach to facilitate guideline updates. This approach is intended to identify new, potentially practice-changing data (i.e., signals) that might translate into revised practice recommendations. The approach relies on routine literature searching and the expertise of ASCO guideline panel members to identify signals. The Methodology Supplement (see the "Availability of Companion Documents" field) provides additional information about the signals approach.

Number of Source Documents

2016 Guideline

Fifty studies comprise the evidence base. They included three meta-analyses, one randomized controlled trial (RCT), 38 prospective-retrospective studies, three prospective comparative observational studies, and five retrospective observational studies.

Also see Data Supplement 5 (see the "Availability of Companion Documents" field) for a Quality of Reporting of Meta-analyses (QUOROM) Diagram showing exclusions and inclusions of publications identified for the systematic review.

2017 Addendum

For this focused update, the publication of the "Microarray in note-negative and one to three positive lymph node disease may avoid chemotherapy" (MINDACT) study, a randomized controlled trial on a 70-gene assay (MammaPrint; Agendia, Irvine, CA) provided the signal.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Guide for Rating Strength of Evidence

Rating for Strength of Evidence	Definition
High	High confidence that the available evidence reflects the true magnitude and direction of the net effect (i.e., balance of benefits versus harms) and that further research is very unlikely to change either the magnitude or direction of this net effect.
Intermediate	Moderate confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research is unlikely to alter the direction of the net effect; however, it might alter the magnitude of the net effect.
Low	Low confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research may change either the magnitude and/or direction this net effect.
Insufficient	Evidence is insufficient to discern the true magnitude and direction of the net effect. Further research may better inform the topic. The use of the consensus opinion of experts is reasonable to inform outcomes related to the topic.

Guide for Rating of Potential for Bias

Rating of Potential for Bias	Definitions for Rating Potential for Risk of Bias in Randomized Controlled Trials
Low risk	No major features in the study that risk biased results, and none of the limitations are thought to decrease the validity of the conclusions. The study avoids problems such as failure to apply true randomization, selection of a population unrepresentative of the target patients, high dropout rates, and no intention-to-treat analysis; and key study features are described clearly (including the population, setting, interventions, comparison groups, measurement of outcomes, and reasons for dropouts).
Intermediate	The study is susceptible to some bias, but flaws are not sufficient to invalidate the results. Enough of the items introduce some uncertainty about the validity of the conclusions. The study does not meet all the criteria required for a rating of good quality, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems.
High risk	There are significant flaws that imply biases of various types that may invalidate the results. Several of the items introduce serious uncertainty about the validity of the conclusions. The study has serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

2016 Guideline

Data Extraction

Literature search results were reviewed and deemed appropriate for full text review by an American Society of Clinical Oncology (ASCO) staff member, in consultation with the Expert Panel Co-Chairs. Data were extracted by one reviewer and subsequently checked for accuracy through an audit of the data by another ASCO staff member. Disagreements were resolved through discussion and consultation with the Co-Chairs if necessary.

2017 Addendum

For this focused update, the publication of the randomized controlled trial on MammaPrint provided the signal. The full ASCO Update Committee was then convened to review the evidence. A summary of the relevant studies on this biomarker can be found in the Data Supplement (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Informal Consensus

Description of Methods Used to Formulate the Recommendations

2016 Guideline

Panel Composition

The American Society of Clinical Oncology (ASCO) Clinical Practice Guidelines Committee (CPGC) and the ASCO Breast Cancer Guideline Advisory Group (GAG) convened an Expert Panel with multidisciplinary representation in medical oncology, radiation oncology, community oncology, statistician, and health outcome researchers, the Practice Guidelines Implementation Network, and patient/advocacy representation. The Expert Panel was led by two Co-Chairs who had the primary responsibility for the development and timely completion of the guideline. The Panel had one face-to-face meeting and three webinars. The Co-Chairs and ASCO staff prepared a draft guideline for review and rating by the Expert Panel. The Expert Panel members are listed in Appendix Table A1 of the original guideline document.

Guideline Development Process

The Expert Panel met on several occasions and corresponded frequently through email; progress on guideline development was driven primarily by the Co-Chairs and ASCO staff. The purpose of the Panel meetings was for members to contribute content, provide critical review, interpret evidence, and finalize the guideline recommendations based upon the consideration of the evidence. All members of the Expert Panel participated in the preparation of the draft guideline document.

Development of Recommendations

The guideline recommendations were crafted, in part, using the GuideLines Into DEcision Support (GLIDES) methodology and accompanying BRIDGE-Wiz™ software. This method helps guideline panels systematically develop clear, translatable, and implementable recommendations using natural language, based on the evidence and assessment of its quality, to increase usability for end users. The process incorporates distilling the actions involved, identifying who will carry them out, to whom, under what

circumstances, and clarifying if and how end users can carry out the actions consistently. This process helps the Panel focus the discussion, avoid using unnecessary and/or ambiguous language, and clearly state its intentions.

2017 Addendum

Guideline Update Process

The Expert Panel met via conference calls to consider the evidence for each of the 2017 recommendations on Mamma Print (Appendix Table A2, online only). The guideline was circulated in draft form to the Expert Panel for review and approval. ASCO's Clinical Practice Guidelines Committee reviewed and approved the final document. Because this was a focused update based on the signal described above, only MammaPrint was reviewed by the Panel for this update.

Rating Scheme for the Strength of the Recommendations

Guide for Types of Recommendations

Type of Recommendation	Definition
Evidence based	There was sufficient evidence from published studies to inform a recommendation to guide clinical practice.
Formal consensus	The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. Therefore, the Expert Panel used a formal consensus process to reach this recommendation, which is considered the best current guidance for practice. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak"). The results of the formal consensus process are summarized in the guideline and reported in the Data Supplement (see the "Availability of Companion Documents" field).
Informal Consensus	The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. The recommendation is considered the best current guidance for practice, based on informal consensus of the Expert Panel. The Panel agreed that a formal consensus process was not necessary for reasons described in the literature review and discussion. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak").
No recommendation	There is insufficient evidence, confidence, or agreement to provide a recommendation to guide clinical practice at this time. The Panel deemed the available evidence as insufficient and concluded it was unlikely that a formal consensus process would achieve the level of agreement needed for a recommendation.

Guide for Strength of Recommendations

Rating for Strength of Recommendation	Definition
Strong	There is high confidence that the recommendation reflects best practice. This is based on (1) strong evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with no or minor exceptions; (3) minor or no concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a strong recommendation.
Moderate	There is moderate confidence that the recommendation reflects best practice. This is based on (1) good evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with minor and/or few exceptions; (3) minor and/or few concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a moderate recommendation.
Weak	There is some confidence that the recommendation offers the best current

Rating for Strength of Recommendation	Definition
	guidance for practice. This is based on (1) limited evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, but with important exceptions; (3) concerns about study quality; and/or (4) the extent of panelists' agreement. Other considerations (discussed in the guideline's literature review and analyses) may also warrant a weak recommendation.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

2016 Guideline

The guideline was then disseminated for external review and submitted to the *Journal of Clinical Oncology* (JCO) for peer review and publication. All American Society of Clinical Oncology (ASCO) guidelines are reviewed and approved by the ASCO Clinical Practice Guidelines Committee (CPGC) prior to publication.

The CPGC approved this guideline on September 21, 2015.

2017 Addendum

The guideline was circulated in draft form to the Expert Panel for review and approval. ASCO's Clinical Practice Guidelines Committee reviewed and approved the final document. Because this was a focused updated based on the signal described above, only MammaPrint was reviewed by the Panel for this update.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

2016 Guideline

A biomarker-based test is judged to have clinical utility if use of the test is associated with a favorable balance of benefits to harms compared with treatment of the patient in the absence of the biomarker test result. Benefits may include improvement in survival end points such as event-free survival (EFS), disease-free survival (DFS), progression-free survival (PFS), or overall survival (OS). A new biomarker test

must be shown to contribute clinically useful information beyond that already provided by clinical or pathologic indicators in standard use, unless the new test can provide equivalent information at lower cost, less invasively, or with less inconvenience or risk. The magnitude of the benefit must be clinically meaningful and outweigh risks, costs, and/or inconvenience associated with use of the test. Refer to the "Clinical Utility" section in the original guideline document for additional discussion.

2017 Addendum

The Use of Biomarkers Update Committee clarified that reduction in toxicity of treatment also can be considered a benefit. For example, a biomarker test that provides evidence that a patient can be treated effectively with hormonal therapy alone provides benefit to that patient by avoiding the potential serious toxicity of chemotherapy.

Refer to the "Clinical interpretation of literature review" sections of the original guideline document and the addendum for a discussion of the relative benefits of testing for specific biomarkers to guide therapy decisions.

Potential Harms

None of the included studies evaluated adverse outcomes of biomarker testing. In addition, no studies reported on changes in quality-of-life outcomes attributable to biomarker testing.

When the panel considered each of the tumor biomarker assay tests, the use context, analytic validity, clinical validity, and clinical utility were considered. For the use context of estimating prognosis to consider whether adjuvant chemotherapy should be administered, the panel recommended use of a tumor biomarker assay if high levels of evidence suggest that it identifies a group of patients for whom the absolute benefit of adjuvant chemotherapy could not exceed 2% to 3%, which is roughly equal to the risk of fatal, life-threatening, or permanently changing toxicities. For other use contexts, the panel's considerations are noted in the appropriate section of the original guideline document.

Qualifying Statements

Qualifying Statements

- The clinical practice guidelines and other guidance published herein are provided by the American Society of Clinical Oncology (ASCO) to assist providers in clinical decision making. The information herein should not be relied on as complete or accurate, nor should it be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. With the rapid development of scientific knowledge, new evidence may emerge between the time information is developed and the time it is published or read. The information is not continuously updated and may not reflect the most recent evidence. The information addresses only the topics specifically identified herein and is not applicable to other interventions, diseases, or stages of disease. This information does not mandate any particular course of medical care. Furthermore, the information is not intended to substitute for the independent professional judgment of the treating provider because it does not account for individual variation among patients. Recommendations reflect high, moderate, or low confidence in the net effect of a given course of action. The use of such words as must, must not, should, and should not indicates that a course of action is recommended or not recommended for either most or many patients, but latitude exists for the treating physician to select other courses of action in individual cases. In all cases, the selected course of action should be considered by the treating provider in the context of treating the individual patient. Use of the information is voluntary. ASCO provides this information on an as-is basis and makes no warranty, express or implied, with regard to the information. ASCO specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. ASCO assumes no responsibility for any injury or damage to persons or

property that arises out of or are related to any use of this information or for any errors or omissions.
- Panel members caution that there are no data to suggest that ordering more than one assay in an individual patient will be helpful to guide treatment decisions and do not recommend the use of more than one test. Clinicians should choose a test that they are most comfortable with to guide treatment decisions.
- Refer to the "Health Disparities," "MCCs" and "Limitation of the Research and Future Directions" sections in the original guideline document for additional qualifying information.

Implementation of the Guideline

Description of Implementation Strategy

American Society of Clinical Oncology (ASCO) guidelines are developed for implementation across health care settings. Barriers to implementation include the need to increase awareness of the guideline recommendations among front-line practitioners, cancer survivors, and caregivers and to provide adequate services in the face of limited resources. The Bottom Line Box facilitates implementation of the present recommendations. This guideline will be distributed widely through the ASCO Practice Guideline Implementation Network. ASCO guidelines are posted on the ASCO Web site and most often published in *Journal of Clinical Oncology* and *Journal of Oncology Practice*.

For information on the ASCO implementation strategy, please see the ASCO Web site .

Implementation Tools

Clinical Algorithm

Patient Resources

Quick Reference Guides/Physician Guides

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Harris LN, Ismaila N, McShane LM, Andre F, Collyar DE, Gonzalez-Angulo AM, Hammond EH, Kuderer NM, Liu MC, Mennel RG, Van Poznak C, Bast RC, Hayes DF. Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline. J Clin Oncol. 2016 Apr 1;34(10):1134-50. [82 references] PubMed

Krop I, Ismaila N, Andre F, Bast RC, Barlow W, Collyar DE, Hammond ME, Kuderer NM, Liu MC, Mennel RG, Van Poznak C, Wolff AC, Stearns V. Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline focused update. J Clin Oncol. 2017 Aug 20;35(24):2838-47. [17 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Apr 1 (addendum released 2017 Aug 20)

Guideline Developer(s)

American Society of Clinical Oncology - Medical Specialty Society

Source(s) of Funding

American Society of Clinical Oncology (ASCO)

Guideline Committee

Expert Panel

Composition of Group That Authored the Guideline

2016 Guideline

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2017 Addendum

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Financial Disclosures/Conflicts of Interest

The expert panel was assembled in accordance with the American Society of Clinical Oncology (ASCO) Conflict of Interest Policy Implementation for Clinical Practice Guidelines (summarized at www.asco.org/rwc). Members of the panel completed the ASCO disclosure form, which requires general disclosure of financial and other interests relevant to the subject matter of the guideline and includes relationships with commercial entities that are reasonably likely to experience a direct regulatory or commercial impact as a result of promulgation of the guideline. Categories for disclosure include employment relationships, consulting arrangements, stock and other ownership interests, speakers' bureaus, honoraria, research funding, intellectual property interests, and expert testimony. In accordance with the procedures, the majority of the members of the panel did not have any such conflicts of interest to disclose.

2016 Guideline

Authors' Disclosures of Potential Conflicts of Interest

The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated. Relationships are self-held unless noted. I = Immediate Family Member, Inst = My Institution. Relationships may not relate to the subject matter of this manuscript. For more information about ASCO's conflict of interest policy, please refer to www.asco.org/rwc or jco.ascopubs.org/site/ifc .

Lyndsay N. Harris: Research Funding: Philips Research

Nofisat Ismaila: Employment: GlaxoSmithKline (I); Stock or Other Ownership: GlaxoSmithKline (I); Travel, Accommodations, Expenses: GlaxoSmithKline (I)

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Fabrice Andre: Research Funding: AstraZeneca (Inst), Novartis (Inst), Pfizer (Inst), Eisai (Inst), Eli Lilly (Inst), Servier (Inst); Travel, Accommodations, Expenses: Novartis, Roche, GlaxoSmithKline

Deborah E. Collyar: Travel, Accommodations, Expenses: Merck

Ana M. Gonzalez-Angulo: No relationship to disclose

Elizabeth H. Hammond: No relationship to disclose

Nicole M. Kuderer: Consulting or Advisory Role: Daiichi Sankyo, Janssen Pharmaceuticals (a Johnson & Johnson co.), Hospira; Research Funding: Amgen (I); Travel, Accommodations, Expenses: Daiichi Sankyo, Janssen Pharmaceuticals (a Johnson & Johnson co.), Hospira

Minetta C. Liu: Research Funding: Eisai (Inst), Seattle Genetics (Inst), Celgene (Inst), Veridex (Inst), Clearbridge Biomedics (Inst), Novartis (Inst), Genentech (Inst)

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Catherine Van Poznak: Research Funding: Bayer AG (Inst); Patents, Royalties, Other Intellectual Property: UpToDate

Robert C. Bast: Research Funding: Arrien Pharmaceuticals; Patents, Royalties, Other Intellectual Property: Fujirebio Diagnostics; Travel, Accommodations, Expenses: Roche

Daniel F. Hayes: Stock or Other Ownership: Oncimmune, Inbiomotion; Honoraria: Eli Lilly; Consulting or Advisory Role: Pfizer, Janssen Diagnostics (unpaid); Research Funding: Janssen Research & Development (Inst), AstraZeneca (Inst), Puma Biotechnology (Inst), Pfizer (Inst), Eli Lilly (Inst); Patents, Royalties, Other Intellectual Property: Royalties from licensed technology; Diagnosis and Treatment of Breast Cancer (Patent No. US 8,790,878 B2; Date of patent: July 29, 2014; Applicant proprietor: University of Michigan; Daniel F. Hayes is designated as inventor/coinventor); Circulating Tumor Cell Capturing Techniques and Devices (Patent No. US 8,951,484 B2; Date of patent: February 10, 2015; Applicant proprietor: University of Michigan; Daniel F. Hayes is designated as inventor/coinventor); A Method for Predicting Progression Free and Overall Survival at Each Follow Up Timepoint During Therapy of Metastatic Breast Cancer Patients Using Circulating Tumor Cells (Patent No. 05725638.0-1223-US2005008602); Travel, Accommodations, Expenses: Janssen Diagnostics

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Authors' Disclosures of Potential Conflicts of Interest

Ian Krop: Employment: AMAG Pharmaceuticals (I); Leadership: AMAG Pharmaceuticals (I); Stock or Other Ownership: AMAG Pharmaceuticals (I); Consulting or Advisory Role: Genentech; Research Funding: Genentech; Other Relationship: Novartis

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Robert C. Bast: Research Funding: Arrien Pharmaceuticals; Patents, Royalties, Other Intellectual Property: Fujirebio Diagnostics, royalties for CA-125 ovarian cancer biomarker; Travel, Accommodations, Expenses: Roche Diagnostics

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Deborah E. Collyar: No relationship to disclose

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Robert G. Mennel: Employment: Texas Oncology

Catherine Van Poznak: Research Funding: Bayer (Inst); Patents, Royalties, Other Intellectual Property: UpToDate

Antonio C. Wolff: Consulting or Advisory Role: Ionis; Research Funding: Myriad Genetics (Inst), Pfizer (Inst); Patents, Royalties, Other Intellectual Property: Named inventor on one or more issued patents or pending patent applications relating to methylation in breast cancer, with rights assigned to Johns Hopkins University (JHU) and participation in a royalty-sharing agreement with JHU.

Vered Stearns: Research Funding: Abbvie, Merck, Pfizer, MedImmune, Novartis, Celgene, Puma Biotechnology

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

2016 Guideline

Available from the Journal of Clinical Oncology Web site .

2017 Addendum

Available from the Journal of Clinical Oncology Web site .

Availability of Companion Documents

The following are available:

2016 Guideline

Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline. Data supplement. Alexandria (VA): American Society of Clinical Oncology (ASCO); 2016. 46 p. Available from the Journal of Clinical Oncology Web site .

Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline. Slide set. Alexandria (VA): American Society of Clinical Oncology; 2016. 24 p. Available in PDF and PowerPoint from the American Society of Clinical Oncology (ASCO) Web site.

Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline. Summary of recommendations. Alexandria (VA): American Society of Clinical Oncology; 2016. 5 p. Available from the American Society of Clinical Oncology (ASCO) Web site .

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Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: focused update of 2016 American Society of Clinical Oncology clinical practice guideline. Methodology supplement. Alexandria (VA): American Society of Clinical Oncology (ASCO); 2017. 19 p. Available from the Journal of Clinical Oncology Web site .

Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: focused update of 2016 American Society of Clinical Oncology clinical practice guideline. Data supplement. Alexandria (VA): American Society of Clinical Oncology (ASCO); 2017. 13 p. Available from the Journal of Clinical Oncology Web site .

Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline focused update. Slide set. Alexandria (VA): American Society of Clinical Oncology; 2017. 25 p. Available in PDF and PowerPoint from the ASCO Web site.

Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline focused

update. Summary of recommendations. Alexandria (VA): American Society of Clinical Oncology; 2017. 5 p. Available from the ASCO Web site .

Patient Resources

The following is available:

Biomarkers to guide treatment for early-stage breast cancer. ASCO care and treatment recommendations for patients. [internet]. Alexandria (VA): American Society of Clinical Oncology (ASCO); 2017 Jul 10. Available from the Cancer.Net Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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